



07-20-01

Docket No: ACY-33261
Patent#5
648
7/25/01IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**RECEIVED**

JUL 24 2001

In re of Application of: **Sanchez, et al.**Serial No.: **09/155,003**Group No.: **1648**

TECH CENTER 1600/2900

Filed: **September 14, 1998** Examiner: **J. Parkin**For: **VECTORS BASED ON RECOMBINANT DEFECTIVE VIRAL
GENOMES AND THEIR USE IN THE FORMULATION OF
VACCINES**Confirmation No.: **7916**Customer Number: **25291**COMMISSIONER FOR PATENTS
BOX NON-FEE AMENDMENT
WASHINGTON, DC 20231**RESPONSE TO RESTRICTION REQUIREMENT**

Dear Sir:

This is in response to the Office Action of June 22, 2001, due July 23, 2001 (July 22, 2001 being a Sunday) comprising a Requirement for Restriction as between the following inventions:

Group I, Claims 46-48, drawn to a recombinant expression vector comprising a defective viral genome encoding a selected antigen;

Group II, claims 46, 47 and 49, drawn to a recombinant expression vector comprising a defective viral genome encoding a selected antibody;

CERTIFICATE OF MAILING 37 CFR §1.10

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EL596536278US addressed to the Commissioner for Patents, Washington, DC 20231.

Date

7-19-01

Lauren Stanilious

Group III, claims 50-52, 55 and 56, drawn to a recombinant expression system comprising an expression vector encoding a selected antigen and helper virus.

Group IV, claims 50, and 53-56, drawn to a recombinant expression system comprising an expression vector encoding a selected antibody and helper virus.

Group V, Claims 57 and 64, drawn to a vaccine comprising an expression vector encoding a selected antibody, a helper virus, and a pharmaceutically acceptable excipient.

Group VI, Claims 57-59, drawn to a porcine vaccine comprising an expression vector encoding a porcine pathogenic immunogen, a helper virus, and a pharmaceutically acceptable excipient;

Group VII, Claims 57, 60 and 61, drawn to a canine vaccine comprising an expression vector encoding a canine pathogenic immunogen, a helper virus, and a pharmaceutically acceptable excipient;

Group VIII Claims 57, 61 and 62, drawn to a feline vaccine comprising an expression vector encoding a feline pathogenic immunogen, a helper virus, and a pharmaceutically acceptable excipient.

It is the position of the Examiner that “the inventions listed as Groups I-VIII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features” and the “claimed invention fails to make a contribution over the prior art.” Further, it is the position of the Examiner that the “application contains claims directed to more than one species of the generic invention” which species lack Unity of Invention because “they are not so linked as to form a single inventive concept under PCT Rule 13.1.”

Responsive to this Requirement, Applicants, with traverse, elect the invention designed as Group VI by the Examiner, *i.e.*, Claims 57-59, drawn to a porcine vaccine

comprising an expression vector encoding a porcine pathogenic immunogen, a helper virus, and a pharmaceutically acceptable excipient. As a species, Applicant elect the species of Claim 59, *i.e.*, porcine pathogens in response to the requirement to elect a species.

Under 35 U.S.C. 121 "two or more independent and distinct inventions ... in one application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, and are patentable over each other" (MPEP 802.01). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

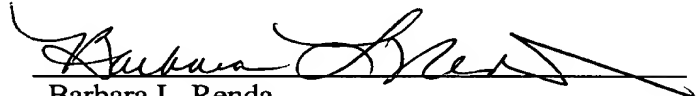
Under Patent Office examining procedures, "If the search and examination of an entire application can be made without serious burden, the Examiner is encouraged to examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988).

In the present instance, the inventive concept is the use of a recombinant expression vector comprising antigens capable of inducing systemic and secretory immune responses against pathogens having tropism for mucosae, or antibodies which confer protection against such pathogens, in combination with a helper virus which provides the functional and structural proteins for the replication and encapsidation of the defective genome. It would therefore follow that a search directed to the helper virus component used in the combination would extend to the relevant areas of classification where the other individual components

themselves would be searched. Thus, contrary to the assertion of the Examiner, the same or corresponding special technical feature is present in each claim. In view of this, Applicants urge that the restriction be withdrawn and that all of the claims of record be examined simultaneously.

For the above reasons, Applicants request withdrawal of the Requirement for Restriction, and early action on the merits as to claims 46-64, presently pending in the case.

No fees are believed to be due for this response. However, should this be in error, authorization is hereby given to charge Deposit Account 01-1300 for any additional fees due.


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